

REMARKS

The foregoing amendments amended claim 30 by incorporating the limitations of claims 31 therein. Claim 31 was canceled accordingly. Editorial changes were made to claims 32 and 33, including changing the dependency of claim 32 from canceled claim 31 to claim 30. Claim 39 and 40 were amended to better define the invention. Accordingly, claims 27-30 and 32-40 remain in the application for consideration by the examiner.

Applicant respectfully requests that the foregoing amendments be entered under the provisions of 37 C.F.R. § 1.116(b) for the purpose of placing the application condition for allowance or for the purpose of appeal. The foregoing amendments are only concerned with editorial matters. In addition, the previous Official action mailed April 10, 2003, set forth two prior art rejections of applicant's claims. Claims 8-12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent No. 4,643,902 of Lawhon (Lawhon). Claims 1-7, 13-14, and 18-25(26) were rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, as obvious under 35 U.S.C. § 103(a) over Lawhon in view of Nakhmedov *et al.* (Koservanaya I Ovoshchesushil'naya Promyshlennost) and British patent specification number 1,007,751 (British '751). In applicant's response filed on September 9, 2003, claims 1-26 were canceled and new claims 27-40 were added to the application. The outstanding Office action does not identify which claims are rejected. Based on the subject matter in the new claims compared to the original claims, it is assumed that claims 30-34 were rejected under 35 U.S.C.

§ 103(a) as being unpatentable over Lawhon, and that claims 27-29 and 35-38 were rejected under 35 U.S.C. § 102(b)/35 U.S.C. § 103(a) over Lawhon in view of Nakhmedov and British '751. The subject matter of claims 39 and 40 does not correspond to a previously presented claimed. Therefore, the applicant cannot determined how (or if) these claims were rejected over the previously cited prior art. The examiner's clarification in this regard is respectfully requested.

For all these reasons, applicant respectfully requests that the foregoing amendments be entered under the provisions of 37 C.F.R. § 1.116(b) for the purpose of placing the application condition for allowance or for the purpose of appeal.

Claims 39 and 40 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Official action stated that the phrases "improving blood fluidity" and "lowering blood pressure" in these claims are relative expressions that render the claims indefinite. The applicant has difficulty understanding this position. It respectfully noted that claims 37 and 38 include phraseology similar to that set forth in claims 39 and 40, but these claims were not rejected under the second paragraph of 35 U.S.C. § 112.

More importantly, applicant respectfully submits that persons skilled in the art precisely understand the meaning of the expressions "improving blood fluidity" and "lowering blood pressure." For example, after a mammal (human)

consumes the composition, food, or drink according to claims 39 and 40, its blood fluidity will be improved relative to its blood fluidity prior to taking the composition, food, or drink. Similarly, a mammal (human) consuming the composition, food, or drink of claims 39 and 40 will have a lower blood pressure relative to its blood pressure prior to consuming the composition food or drink. In addition, applicant respectfully note that the present specification disclosure discusses blood fluidity improvement and blood pressure lowering of the compositions of applicant's claims at page 7, first complete paragraph; page 12, first complete paragraph; the paragraph bridging pages 28 and 29; the first two complete paragraphs on page 29; and elsewhere. For all these reasons, applicant respectfully submits that one of ordinary skill in the art would attach a particular and definite meaning to the expressions "improving blood fluidity" and "lowering blood pressure," as set forth in claims 39 and 40.

In order to expedite the allowance of the present application, claims 39 and 40 were amended above to recite "improving... compared to... before the ingestion of the composition." For all the foregoing reasons applicant respectfully submits that claims 39 and 40 particularly point out and distinctly claim the subject matter regarded as the invention within the meaning of 35 U.S.C. § 112, second paragraph. Therefore, applicant respectfully requests that the examiner reconsider and withdraw this rejection.

Applicant respectfully submits that the teachings of Lawhon, Nakhmedov *et al.* (Nakhmedov) and/or British '751 do not disclose or suggest the invention

as set forth in the present claims within the meaning of 35 U.S.C §102 or 35 U.S.C §103.

At the bottom of page 3 the Official action stated that the rejection over Lawhon was maintained. In response to applicant's argument that Lawhon does not contemplate or suggest a "charged" reverse osmosis membrane, the Official action noted example 4 in column 10 of Lawhon, as proposing the use of a membrane having a 99% rejection for NaCl. The Official action apparently interpreted this portion of Lawhon as meaning or requiring that membranes having a 99% rejection for NaCl must necessarily be a "charged" reverse osmosis membrane. In other words, appears to be the position of the Patent Office that in order for a membrane to have a 99% rejection for NaCl, it must be a charged reverse osmosis membrane. Applicant respectfully submits that such reasoning is not correct. In order to maintain such a position, applicant respectfully submits that a teaching reference in support this position must be set forth. In addition, it is respectfully noted that uncharged reversed osmosis membranes can have a retention rate of 99% in the case of NaCl, which is discussed in the first complete paragraph on page 19 of the present specification. Accordingly, applicant respectfully submits that reasoning the forth in the Office action is fundamentally flawed and the teachings of Lawhon cannot possibly contemplate or suggest the use of a charged reversed osmosis membrane, as required in the present claims.

In more detail, it is respectfully noted that the Official action stated that the reverse osmosis membrane used by Lawhon is aided by charged particles.

However, the charged reverse osmosis membrane used in the presently claimed invention is structurally and functionally different from the reverse osmosis membrane proposed by Lawhon, and therefore the product obtained by the method using the charged reverse osmosis membrane in applicant's claims is necessarily different from the product obtained by the Lawhon's process.

In the presently claimed process, the charged reverse osmosis membrane is used to separate anthocyanin from other components, such as sugars and acids, and to concentrate the anthocyanin to 1% or more on the basis of solid matters. The molecular weight fractionated by the charged reverse osmosis membrane used for the present process is generally 3,000 to 5,000. On the contrary, the reverse osmosis membrane used in Lawhon fractionates molecules of which molecular weight is a little larger than a water molecule. Accordingly, the charged reverse osmosis membrane of the present claims is different from the reverse osmosis membrane of Lawhon and, therefore, the components obtained by the charged reverse osmosis membrane of the present claims is different from those obtained by reverse osmosis membrane disclosed in Lawhon.

The charged reverse osmosis membrane is used to purify solid materials from a solution. The present specification describes that the salt retention rate of the charged reverse osmosis membrane of applicant's claims is 5 to 20%. The salt retention rate means the amount of salt which is retained in a reverse osmosis retentate. That is, "the salt retention rate of 5 to 20%" means that 5 to 20% of salt is retained in the retentate and 80 to 95% of salt is permeated in

the permeate. On the contrary, since reverse osmosis membrane as used within the teachings of Lawhon is mainly used for the specified purpose of, for example, to prepare pure water from sea water, the salt rejection rate means the rate of the rejection of salt in the permeate. Therefore, 99% of salt rejection rate of the reverse osmosis membrane in Lawhon means that 99% of salt is retained in the retentate. Therefore, even in view of the salt retention, the charged reverse osmosis membrane of the presently claimed invention is significantly different from the reverse osmosis membrane disclosed in Lawhon.

Consequently, the charged reverse osmosis membrane of the present claims is different from the reverse osmosis membrane of Lawhon in properties. By using the charged reverse osmosis membrane of the present claims, the two fractions (i) and (ii) below were obtained (See Figure 1 attached hereto, which illustrates the process of both of the present invention and that of Lawhon.).

- (i) reverse osmosis retentate including anthocyanin and other high molecular weight components
- (ii) reverse osmosis permeate including flavor and aroma components, sugars, acids, water and salts

Since the molecular weight of anthocyanin is about 500, one of ordinary skill in the art would expect that anthocyanin would be included in the reverse osmosis permeate. However, unexpectedly and surprisingly, anthocyanin is included in the reverse osmosis retentate. This unexpected and surprising property of the charged reverse osmosis membrane is used in the invention of applicant's claims. In the process of the presently claimed invention,

anthocyanin can be unexpectedly and surprisingly separated from flavor and aroma components, sugars, acids, water and salts and therefore purified by a process including use of a charged reverse osmosis membrane.

On the contrary, the process proposed by Lawhon is concerned with a process to produce fruit juice -- not to purify anthocyanin as presently claimed. In the conventional process to produce fruit juice, whole fruit juice is heated for sterilization of microorganism included in the fruit juice. However, the sterilization also reduces the flavor and aroma components. In Lawhon's process, an ultra filtration (UF) membrane is used to inhibit the reduction of the flavor and aroma components. In the process, fruit juice is fractionated into a retentate and permeate by using the UF membrane. The retentate includes microorganisms to be deleted as well as high molecular weight components and sugars. The permeate includes anthocyanin, sugars, acids, flavor and aroma components. The retentate only is heated for sterilization. The permeate is not heated since it never includes microorganisms to be deleted. After the retentate is heated, it is mixed with the permeate to produce a fruit juice containing no microorganism. Furthermore, on one embodiment of the Lawhon's process, the UF permeate is further subjected to reverse osmosis membrane separation and the flavor components and aroma components are concentrated into the retentate.

Lawhon proposes in its explanation of reverse osmosis membrane that the semipermeable membrane is used to make a solvent (in case of juice, water) pass through and retain other components such as anthocyanin, sugars, acids,

flavor and aroma components. This is demonstrated by tables 4 and 5 which indicates that the reverse osmosis permeate does not include solid components and sugars. In the Lawhon's process, a juice is separated into 3 fractions (a) to (c) below by UF membrane treatment followed by reverse osmosis membrane treatment (See Figure 1 attached hereto.).

- (a) UF retentate including enzymes and microorganisms to be inactivated and sterilized
- (b) reverse osmosis retentate from UF permeate, including flavor components, aroma components, sugars and acids
- (c) reverse osmosis permeate of UF permeate mainly including water and including little solids

Accordingly, in the process proposed by Lawhon, the important anthocyanin is mainly present in (b) above and partially present in (a) above. Thus, in the process proposed by Lawhon, fractions (a) to (c) are mixed to obtain general juice as obtained by squeezing fruits as indicated in Fig. 1. Alternatively, fractions (a) and (b) only are mixed to obtain concentrated juice and fraction (c) is discarded.

As described above, anthocyanin is included in retentate of reverse osmosis membrane together with sugars and acids and is not never purified in the process proposed by Lawhon. On the contrary, in the presently claimed process, since anthocyanin is separated in the retentate and sugars and acids are separated in the permeate, anthocyanin can be purified.

As illustrated in the attached Figure 1, the anthocyanin-containing composition of the present invention is never produced by the process proposed by Lawhon, since the fraction including anthocyanin without water, sugars and acids cannot be obtained by the process proposed by Lawhon.

Consequently, the teachings of Lawhon never contemplate or suggest a process to purify anthocyanin of the present invention, so as to obtain the presently claimed anthocyanin-containing composition in which anthocyanin is purified to be included in 5 to 25% by weight of black currant anthocyanin on the basis of solid matters. For all these reasons, applicant respectfully submits that it is impossible for the teachings of Lawhon to contemplate or suggest the presently claimed invention within the meaning of 35 U.S.C §102 or 35 U.S.C §103. Therefore, applicant respectfully request that the examiner reconsider and withdraw any and all rejections of the present claims over these teachings.

In the response filed on September 10, 2003, the meaning of “mg%” within the teachings of Nakhmedov was discussed. However, the outstanding Office Action does not mention this important teaching. For a better understanding of these teachings, the disclosures of Nakhmedov are explained again here and an English translation of Nakhmedov is attached hereto. Nakhmedov never discloses the composition including anthocyanin of the claimed composition of the present claims. The reference cited by the Patent Office uses the unit “mg%”. However, the original literature in Russian does not use this unit. It uses the unit “mg/100g”. The original literature in Russian and the English translation thereof, both of which are attached hereto,

show this. Table 1 of Nakhmedov shows that approximately 800-2000 mg/100g of anthocyanin is contained in the pomace of black currant which is corresponding to 0.8 to 2% of anthocyanin. Accordingly, Nakhmedov never contemplates or discloses the presently claimed composition.

The teachings of the British '751 do not cure or rectify the deficiencies in the teachings of Nakhmedov. For example, the teachings of the British '751 do not contemplate or suggest black currant concentrate and, therefore, cannot contemplate or suggest specific amounts of black currant anthocyanin, as required in the present claims.

An advantage of the composition of the present claims is that it can be used as a food or a food additive. This is because the composition of the present claims has excellent stability against spoilage and reduced acidity. In this connection, it is respectfully noted that the teachings of Nakhmedov state that the materials proposed therein were contaminated and spoiled easily, meaning it is not suitable as a food or a food additive. This statement in Nakhmedov evidences the fact that the composition proposed therein is different from that defined in the present claims.

The pharmacologic effects of anthocyanin other than those derived from black currant anthocyanin on peripheral arteries are the effect as pharmaceuticals not as foods. The presently claimed composition made it possible to utilize the pharmacologic effects of black currant anthocyanin in foods. Furthermore, the only previously known effect of anthocyanin was the effect on arteries. On the contrary, black currant anthocyanin of the present

invention acts on blood to improve blood fluidity and lower blood pressure as the result of example 12 of the present specification shows.

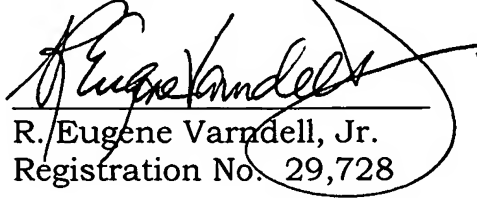
For the reason set forth above, applicant respectfully submits that the present claims are distinguishable from the teachings of Lawhon, Nakhmedov, and/or British '751 within the meaning of 35 U.S.C. § 102 or 35 U.S.C. § 103. Therefore, applicant respectfully requests that the examiner reconsider and withdraw this rejection.

For the foregoing reasons, applicant respectfully requests that the examiner reconsider and withdraw all the objections and rejections set forth in the Official action mailed November 25, 2003, so that all pending claims 27-30 and 32-40 will be allowed.

The foregoing is a complete and proper response to the Official action mailed November 25, 2003. Should the examiner have any comments or questions, it is respectfully requested that the undersigned be telephoned at the below listed number to resolve any outstanding issues.

In the event that this paper is not timely filed, applicant hereby petitions for an appropriate extension of time. The Commissioner is hereby authorized to charge the fee therefor, as well as any deficiency in the payment of the required fee(s) or credit any overpayment, to our deposit account No. 22-0256.

Respectfully submitted,
VARNDELL & VARNDELL, PLLC
(formerly Varndell Legal Group)



R. Eugene Varndell, Jr.
Registration No. 29,728

Atty. Case No. VX012397
106-A S. Columbus St.
Alexandria, Virginia 22314
(703) 683-9730
\\V:\VDOCS\W_DOCS\APR04\IP080-2397 RSAF.DOC

